



Ob/Gyn & Women's Health Institute

2017 Year in Review

MESSAGE FROM THE CHAIRMAN



Dear Colleagues,

I am pleased to provide you with this brief review of our obstetrics, gynecology and women's health activities at Cleveland Clinic. As you will read in this *Ob/Gyn & Women's Health Institute 2017 Year in Review*, our group has made significant contributions to improving the health and well-being of women through clinical care, research and education.

We continue to shape the future of surgery by investigating the least invasive, most precise procedures to produce the best outcomes for women facing a range of conditions — from cancer, pelvic floor disorders, fibroids and endometriosis to gender reassignment.

We have pushed the boundaries of research in gynecological cancers and other disorders, both at the bench and bedside, through collaborative, multicenter studies on five continents.

We have expanded services for pregnant women, including a specialized maternal cardiac clinic and leading-edge procedures such as fetal surgery.

We have made important advances for our patients facing fertility and weight management issues.

As Cleveland Clinic Lerner College of Medicine educators, we continue to train medical students and Ob/Gyn residents and fellows on the verge of exciting careers.

We continue to share knowledge with colleagues around the world through courses and lectures

presented at Cleveland Clinic and at national and international medical meetings, and through our surgical videos.

As members of a global community, we offer our residents and fellows the opportunity to participate in research and education in many countries.

We continue to lead healthcare transformation by taking leadership roles in our national societies.

Thank you for taking a few moments to read this *Year in Review*. The narratives presented represent the hard work of a marvelous team, which I am honored and proud to lead. I thank my team for their talent, intelligence and devotion to serving our — and your — patients.

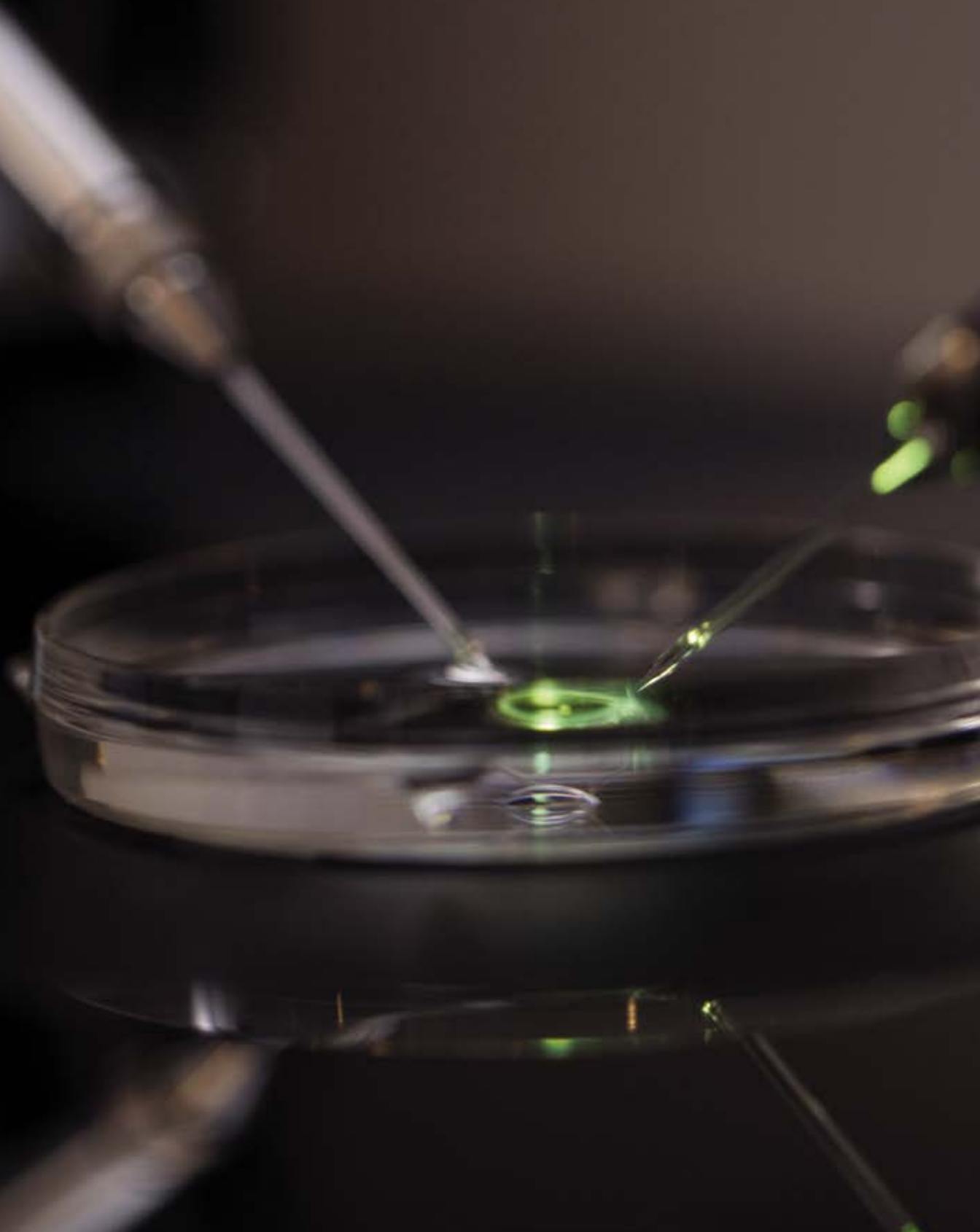
I look forward to continued productive relationships with valued colleagues across the country in pursuit of our shared goals in research, in education and above all in the care of patients facing the full range of women's health issues.

Your comments and contacts are always welcome.

Sincerely,



Tommaso Falcone, MD, FRCSC, FACOG
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and Gynecology
Chairman, Ob/Gyn & Women's Health Institute
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Going Beyond Looks:

The Road to Single Embryo Transfers in IVF

Just 25 years ago, only 1 in 10 women undergoing fertility treatment went home with a baby. To be successful, a woman needed to accept the transfer of three or four embryos to her uterus, despite the increased risk of multiple births and associated neonatal and maternal complications.

Moreover, embryos were introduced into the uterus at the two- to eight-cell stage. The single most important criteria for embryo selection was simply morphology at transfer, explains Nina Desai, PhD, HCLD, who heads Cleveland Clinic's In Vitro Fertilization (IVF) laboratory, located at Cleveland Clinic Beachwood.

Advances in clinical and laboratory protocols have since changed the overall landscape of IVF, with higher live birth rates and fewer embryos being transferred. And yet morphology has remained the predominant embryo selection criterion.

"In the last five years, two new technologies — time-lapse imaging and preimplantation genetic screening (PGS) — have been adopted by clinics to get beyond 'looks' in embryo selection for transfer," says Dr. Desai.

Time-lapse imaging and EmbryoScope®

Cleveland Clinic introduced time-lapse imaging into its fertility practice in 2012. By 2014, Dr. Desai and colleagues began using continuous undisturbed culture in the EmbryoScope for all patients. This meticulously engineered incubation chamber uses sophisticated video capabilities to produce time-lapse images of embryos as they grow.

"The wealth of information this technology provides allows us to assess the implantation potential of embryos using cell-cycle kinetics and visualization of nuclear and cleavage anomalies," Dr. Desai says. "We use this technology routinely to identify high-potential embryos and transfer them singly to patients, helping achieve a healthy outcome for mother and child."

Preimplantation genetic screening

Embryonic aneuploidy contributes significantly to failed implantation. PGS addresses this issue by selecting embryos based on chromosome status rather than morphology.

"This represents a significant shift in IVF practice, and most importantly, allows patients to elect to transfer a single euploid embryo and have a high expectation of a positive outcome," Dr. Desai says. "Pregnancy rates with transfer of a single euploid blastocyst range from 55 to 65 percent in our IVF program." She notes, however, that PGS is quite expensive and very labor-intensive and invasive, requiring excision of cells from the blastocyst using a laser.

Examining embryo selection methods

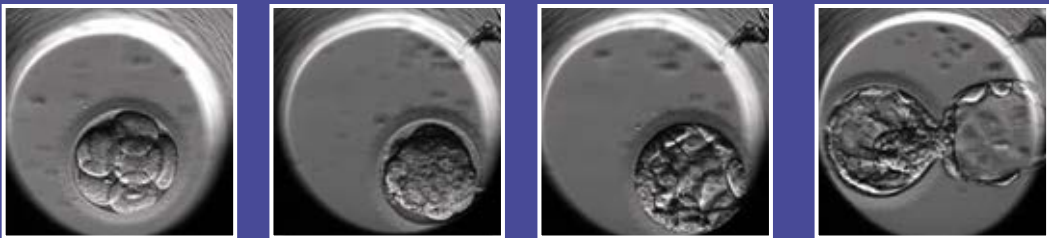
A new study from Dr. Desai's laboratory looks at the correlation between embryo growth kinetics and chromosome status with an eye toward finding a less invasive method to select euploid embryos.

"Preliminary data do indeed indicate that morphokinetic data available from time-lapse imaging may enhance the likelihood of selecting chromosomally normal embryos," she says. "This is an intriguing possibility, and we hope to exploit such information to help our patients."

On the policy front

"The adoption of a single embryo transfer policy is imperative for the health of our patients and their babies," Dr. Desai continues. "However, this demands not only optimization of culture technology, but also embryo selection/deselection techniques."

Development of noninvasive screening methods to assess embryo viability and implantation potential is the newest challenge in IVF, and it is an imperative one as we continue to encourage elective single-embryo transfers.



Nina Desai, PhD, HCLD



Linda D. Bradley, MD, and
resident Thanh Ha Luu, MD

Embracing Hysteroscopy:

Indications Span a Vast Array of Common Problems

With an estimated 90 percent of hysterectomies performed for non-life-threatening indications, including uterine fibroids and uterine bleeding, Cleveland Clinic gynecologist Linda D. Bradley, MD, Director, Menstrual Disorders, Fibroids and Hysteroscopic Services Center, is an outlier.

To effectively reduce the need for hysterectomies, Dr. Bradley champions hysteroscopy for the evaluation of patients with abnormal menstrual periods, infertility, recurrent miscarriage, retained products of conception, endometrial polyps, intrauterine fibroids, abnormal bleeding and, in some cases, abnormal Pap results. Over time, she has convinced her colleagues in the Ob/Gyn & Women's Health Institute to carry the hysteroscopy banner, and she urges others to do the same.

Scopes in many practices

"Urologists use cystoscopes to investigate urinary tract bleeding with hematuria. Pulmonologists use bronchoscopes for patients who are coughing up blood. An orthopod will use an arthroscope to look inside a painful knee," Dr. Bradley notes. "Yet unlike other specialists, gynecologists have not fully embraced hysteroscopes for symptomatic problems.

"My hysteroscope is my stethoscope!" says Dr. Bradley, also the institute's Vice Chair. She adds that hysteroscopy offers multiple benefits for physicians and patients alike.

"Hysteroscopy can be a comfortable, office-based, economical technique for taking a look, and the best use of time and resources," she says. "It enables me to evaluate endometrial health and then plan the appropriate surgical procedure or make a referral."

Typical hysteroscopy cases

Dr. Bradley and her colleagues generally perform 15 to 20 office hysteroscopies per week. The following scenarios are typical:

- A 45-year-old woman with irregular, but heavy bleeding. Absent any polyps, submucosal fibroids or endometrial hyperplasia, the patient could be treated medically.
- A patient with heavy menstrual bleeding. If a fibroid or fibroids are seen, their size, number and location can help determine which technology is required for surgery and the likely duration of the procedure.
- A 48-year-old with abnormal bleeding. Studies have shown that biopsies can miss cancerous lesions involving less than 25 percent of the uterine cavity. Hysteroscopy will detect even small lesions.
- A patient who miscarried and continues to bleed after a dilation and curettage. Even small placental remnants can cause bleeding for weeks or months. "I have found placental remnants in a 70-year-old," Dr. Bradley comments.
- An asymptomatic 30-year-old who cannot get pregnant. An asymptomatic fibroid or endometrial polyp may be filling the uterus and preventing pregnancy.

Dr. Bradley also advocates using operative hysteroscopy to remove submucosal and endometrial polyps. "Operative hysteroscopic myomectomy provides excellent outcomes, carries a low risk of complications and preserves fertility," she notes.

A thorough review of the procedure was published in *Operative Techniques in Gynecologic Surgery: Gynecology*, co-edited by Dr. Bradley. "There are so many reasons to make hysteroscopy part of your armamentarium," she says.

Predicting Risk of Infection After Cesarean Delivery: An Accurate New Personalized Assessment Tool

Over 1 million cesarean deliveries were performed in the United States in 2014, accounting for 32 percent of all births. Estimates of postoperative infection after cesarean delivery range from 3 to 20 percent, depending on institution and geographic location. These infections significantly increase healthcare costs due to hospital readmissions, reoperations and home healthcare needs.

“In current obstetrical practice, providers have few strategies to counsel a woman regarding her specific risk of developing an infection in the postpartum period,” says Oluwatosin Goje, MD, MSCR, who leads the Gynecologic Infectious Diseases Program.

To address this issue, Dr. Goje and Cleveland Clinic colleagues developed and validated a statistical model, or nomogram, that can predict a woman’s individual probability of developing an infection after cesarean delivery. The nomogram takes into account multiple risk factors, including gestational age, body mass index, number of previous cesarean sections, history of asthma and several other factors. It has proven accurate in predicting infection approximately 70 percent of the time.

“The net benefit of the model is that it identifies 35 more cases per 1,000 without increasing the number treated unnecessarily when compared with treating all patients with prophylactic antibiotics plus additional therapy (e.g., more antibiotics),” Dr. Goje says. The study was published in the *Journal of Maternal-Fetal & Neonatal Medicine*.

Infections grouped to provide a single estimate of risk

The researchers collected data retrospectively from all women who underwent cesarean delivery at Cleveland Clinic hospitals between January and December 2013. The target outcome was defined as diagnosis of any infection attributable to the surgical procedure

within 30 days after delivery. Surgical site infections, urinary tract infections, endomyometritis, pneumonia, *Clostridium difficile* infections and blood stream infections were included.

“All postpartum infections were grouped into one infectious outcome to determine a single estimate of risk, making it easy for providers and patients to understand and helping guide management of postpartum infection,” Dr. Goje explains.

When to elevate therapy

“If risk is elevated above a certain threshold, clinicians might consider additional therapy or closer surveillance during the postoperative period,” Dr. Goje explains. The model also supports the informed consent process by providing a better estimation of risks to the patient, which may heighten the patient’s awareness of signs and symptoms of infection in the postoperative period.

“Our nomogram provides obstetrical providers and patients with an accurate, personalized and tangible assessment of their individualized risk of developing an infection within the first 30 days after cesarean,” Dr. Goje says.

“The strength of our model is that it combines risk factors into a single prognostic probability that is easily interpretable for the clinician and patient,” she concludes. “While many unique risk factors do contribute to each individual infection, our model provides a simple risk assessment that is helpful for patient counseling and treatment planning based upon patient, surgical and obstetrical variables.”

Identification of patients at risk for postoperative infection allows for implementation of multidisciplinary strategies for infection reduction and patient-specific counseling.



Oluwatosin Goje, MD, MSCR



Cecile Unger, MD

Multidisciplinary Team Expanding Care for Transgender Patients at Cleveland Clinic

Two new patient care centers at Cleveland Clinic demonstrate the system's commitment to meeting the unique healthcare needs of the LGBTQ community. The Center for Lesbian, Gay, Bisexual and Transgender (LGBT) Care opened within primary care practices at two Cleveland locations. A major part of the center's mission is to help transgender patients access the care they need.

"For decades, providers with varying clinical backgrounds have provided basic healthcare and certain transgender-specific services," says urogynecologist Cecile Unger, MD, Director of Cleveland Clinic's Transgender Surgery and Medicine Program. "However, access has often been challenged by multiple barriers, including a shortage of providers willing and able to care for these patients." Cleveland Clinic's Center for LGBT Care offers comprehensive, compassionate care for all patients regardless of sexual orientation or gender identity.

"The biggest deficit has been in comprehensive care for transgender patients specifically," Dr. Unger continues. "Recognizing the need to provide comprehensive services to transgender patients, our enterprise has supported the development of a multidisciplinary team of medical providers to care for these patients. Our mission is to provide world-class care in a safe environment that maintains the respect and dignity of all patients, and to offer educational initiatives for medical professionals on the care of trans patients."

Multiple specialties involved

The team offers routine medical care, tailored specifically to patients' needs, as well as transition-specific services. These include psychiatric assessment and therapy; hormone therapy and surveillance; and gender-affirming procedures, including gender confirmation surgery.

The transgender team includes specialists from internal medicine, gynecology, psychiatry, endocrinology, female pelvic and reconstructive surgery, urology, and plastic surgery. Pediatric and adolescent medicine specialists are also an important part of the team, as are nurses and a program coordinator. In addition, the team often partners with specialists from digestive diseases, cardiology and other areas to address other health concerns.

Gender affirmation surgery

Previously referred to as sex reassignment surgery, gender affirmation surgery (male-to-female vaginoplasty) is currently performed by about a dozen U.S. surgeons. At Cleveland Clinic, a team including female pelvic medicine and reconstructive surgery fellows, Ob/Gyn residents, and Dr. Unger perform two to three genital surgeries for transgender women each month. The program has become very busy as a result of improved commercial and government-sponsored insurance coverage for transgender-specific services. "We are now booking about six months out," Dr. Unger notes.

Education is paramount

Historically, physicians received training in this area through apprenticeships. "Integrating surgical care for transgender women into training programs is becoming a priority," says Dr. Unger. "We plan to develop a research initiative to help track outcomes and advance this surgical subspecialty."

Because few LGBT clinics exist, patients travel to Cleveland Clinic's Center for LGBT Care from throughout Northeast Ohio, as well as Pennsylvania, New York and other states.

Two Studies Provide Guidance for Gynecologists in the Treatment of Endometriosis

Among the many studies Cleveland Clinic gynecologists published in 2016 and 2017, two shed new light on best practices in managing women with endometriosis.

“Gynecologists know endometriosis as a chronic, inflammatory, estrogen-dependent disease associated with significant quality-of-life challenges, including pain and infertility,” says Tommaso Falcone, MD, Chairman of the Ob/Gyn & Women’s Health Institute. “Endometriosis has a substantial economic impact in terms of decreased productivity and healthcare costs. Our research is aimed at improving understanding, diagnosis and treatment of this disease, and we feel it is extremely important to share knowledge with colleagues around the world.”

Surgery and ovarian reserve

The first study, the “Effect of Surgery on Ovarian Reserve in Women with Endometriomas, Endometriosis and Controls,” was published in the *American Journal of Obstetrics and Gynecology*. The study’s goal was to determine the impact of surgical excision of endometriosis and endometriomas on ovarian reserve compared with control subjects.

The research included 116 women ages 18 to 43 who presented with pelvic pain and/or infertility and who underwent surgical management for suspected endometriosis or endometriomas.

Researchers used anti-Müllerian hormone (AMH) to measure ovarian reserve. They found that baseline AMH values were significantly lower in the endometrioma group compared with the negative laparoscopy group. Only patients with endometriomas had a significant decline in ovarian reserve at one month. Six months after surgery, AMH values

were no longer significantly different from baseline, demonstrating some recovery from surgery.

“At baseline, patients with endometriomas had significantly lower AMH values compared with women without endometriosis,” Dr. Falcone notes. “Surgical excision of endometriomas appears to have temporary detrimental effects on ovarian reserve. Clinically, this means that we should carefully consider the long-term impact on fertility when we remove an endometrioma.”

LAROSE: Robotic versus nonrobotic surgery

Contrary to the common expectation that robotic assistance improves outcomes of endometriosis surgery, Cleveland Clinic researchers found no evidence it is either superior or inferior to traditional laparoscopic technique. This study was published in *Fertility & Sterility*.

The primary outcome measure in the Laparoscopy Versus Robotic Surgery for Endometriosis (LAROSE) trial was operative time, while secondary outcomes included perioperative complications and quality of life. No difference in operative time was seen between the robotic and traditional laparoscopic surgery groups. Nor were there differences in blood loss, intraoperative complications, postoperative complications, rates of conversion to laparotomy or quality-of-life improvement.

“Both robotic and laparoscopic surgery improve quality of life and relieve pain when the procedures are done by experts in endometriosis,” Dr. Falcone notes.

“Knowledge of the disease process and what the disease looks like in a patient plus familiarity with the anatomy are more important to outcomes than the surgical technique or technology used,” he says, adding, “If you are a good driver, it’s unlikely that a more expensive car, say a Ferrari, will make you drive better. It’s the same with surgery. The robot isn’t magical.”



ENDOMETRIOSIS CENTER

The Ob/Gyn & Women's Health Institute includes an Endometriosis Center with a unique multidisciplinary team consisting of pain management specialists; specialty-trained gynecologic, urologic and colorectal surgeons; infertility specialists; and special imaging experts. Highly personalized patient care is combined with robust research, training and continuing medical education functions.



Ofer Reizes, PhD

Gynecologic Oncology Research: Battling Chemoresistance and Recurrence in Endometrial Cancer

The research teams of Ofer Reizes, PhD, and Justin Lathia, PhD, recently discovered a key pathway that leads to recurrence and treatment resistance in endometrial cancer.

For the past 25 years, standard therapy for endometrial and ovarian cancers has included surgery and cisplatin. After an initial response, however, the cancer often recurs and becomes resistant to cisplatin, leaving patients with limited treatment options. In recent years, it has become apparent that recurrence and chemoresistance may be attributed to a subset of cancer cells called cancer stem cells (CSCs).

Drs. Reizes and Lathia are in the Department of Cellular and Molecular Medicine in Cleveland Clinic's Lerner Research Institute. Dr. Reizes holds the Laura J. Fogarty Endowed Chair for Uterine Cancer Research.

The researchers identified a unique role of CD55, an immune regulatory protein found to be abundant on the surface of endometrioid ovarian cancer and uterine cancer cells and particularly high on CSCs.

Drs. Reizes and Lathia showed that CD55 is unique because it controls both tumor recurrence and therapeutic resistance mechanisms. In cellular studies and preclinical mouse studies, the investigators showed that blocking CD55 in chemoresistant endometrial cancer sensitized the tumors to cisplatin.

The team plans to complete further preclinical testing and then begin a clinical trial in patients with CD55-expressing endometrial cancers.

"Endometrial cancer is the most common gynecologic malignancy in the United States, yet this area of research is understudied and underfunded," Dr. Reizes says. "We hope that our study will lead to much-needed new therapy options for women with treatment-resistant relapsed disease."

Vitrification of Ovarian Tissue Offers New Hope for Fertility Preservation for Pediatric and Adult Patients

Six-year-old Maddie* was enjoying a typical childhood summer with her parents in 2015. But a diagnosis of aplastic anemia changed her life suddenly and dramatically.

In severe cases like Maddie's, bone marrow transplant is the next step when first-line treatments fail. Although often very successful, bone marrow transplants and other cancer treatments are gonadotoxic. They often cause hormone and menstrual abnormalities at the very least, and more often cause irreversible ovarian damage or premature menopause that renders young women completely infertile as adults.

Maddie's Cleveland Clinic pediatric hematologist-oncologist Rabi Hanna, MD, decided to refer Maddie and her family to Rebecca Flyckt, MD, at Cleveland Clinic Fertility Center to discuss fertility preservation options prior to her undergoing a bone marrow transplant.

Options for young girls

"Until recently, options to protect and preserve fertility in women prior to cancer treatment have been limited, including the gold-standard egg and embryo freezing," notes Dr. Flyckt. "Plus, it is available only to postpubertal females, meaning girls and young teenagers facing cancer treatment had no options to preserve fertility."

In addition, egg and embryo freezing may not be possible or desirable for adult women who cannot delay cancer treatment or who cannot participate in expensive and involved in vitro fertilization (IVF) procedures for other reasons.

Promising new approach

Over the past several decades, a promising new approach to preserve fertility in younger patients and older women ineligible for egg and embryo freezing — ovarian tissue freezing using vitrification — has come to the fore.

"Although still considered experimental by professional societies such as the American Society for Reproductive Medicine, to date over 100 live births have been reported worldwide using this technique," Dr. Flyckt reports.

"Vitrification (rapid tissue freezing), which is similar to current methods used to store embryos at IVF centers, eliminates ice crystal formation, the major limiting factor in older, slow-freezing techniques," she explains. "Ovarian tissue freezing can preserve the entire ovary and potentially thousands of viable oocytes."

Ovarian cortical tissue is harvested through a simple laparoscopic procedure with same-day discharge and minimal surgical risk. Tissue is frozen in strips and can be stored for decades. When the woman is ready to pursue pregnancy, tissue is reimplanted either at the site of the ovary (orthotopic transplant) or in an alternate location (heterotopic transplant). The tissue, secured with fine sutures, can then develop a healthy blood supply. Normal endocrine and reproductive function resumes, offering the opportunity for assisted reproduction or spontaneous pregnancy. No immunosuppression is needed.

Cleveland Clinic experience

Cleveland Clinic's Fertility Center offers ovarian tissue freezing for adults, teenagers and prepubescent girls who face treatments that diminish fertility.

"The true advantages of this technique are that patients do not need to have completed puberty — so the youngest of our patients are eligible. It also does not delay treatment," Dr. Flyckt says. But she cautions, "We do not know whether ultimately it will be as successful as other established techniques."

As for Maddie? After careful discussion and planning among family members and caregivers, she became the youngest patient to undergo the ovarian tissue freezing process at Cleveland Clinic. She is doing extremely well, is off all major medications and living a normal life.

*A pseudonym.



Rebecca Flyckt, MD



The new home of Cleveland
Clinic cancer care



Gynecologic Oncology at Home in New Cancer Center

Our gynecologic oncologists and patients moved into a modern, light-filled, state-of-the-art building this year. The new Cleveland Clinic Cancer Center brings together all main campus oncology services into one beautiful outpatient tower.

The \$276 million facility, opened in March 2017, makes possible seamless care coordination between our team of gynecologic oncologists and multiple disciplines participating in our patients' care.

"We have our own dedicated clinical practice floor, putting physicians steps away from patients," says Peter G. Rose, MD, Section Head of Gynecologic Oncology. "Exam rooms surround a meeting space where members of the multidisciplinary team — gynecologic oncologists, radiologists, palliative care providers, oncology nurses and advanced practice providers — can discuss the course of treatment for each patient."

With consolidated offices and clinical facilities and advanced scheduling, the new cancer center minimizes wait and transit times and maximizes convenience. "More often than not, patients are in one place, and our practitioners come to them," Dr. Rose adds. "At the end of their visit, most new patients leave with a personalized treatment plan in hand."

Diagnostic imaging or radiotherapy services are located in the basement. The first floor houses reception, an expansive hematology laboratory and blood-drawing stations, a retail pharmacy, and patient services, including a café, wellness center (yoga classes, massage therapy), wig boutique and more.

The second floor includes a dedicated area for phase I clinical trials, chemotherapy and patient monitoring. "This reflects Cleveland Clinic Cancer Center's aggressive efforts to expand access to phase I clinical trials," Dr. Rose remarks. "Research continues to be a cornerstone of our Gynecologic Oncology Program. Our robust clinical trial portfolio continues to grow, offering patients new and innovative treatment options."

Advanced therapeutic capabilities

In addition to phase I clinical trials and other trials available through the international research alliance, NRG Oncology, the institute offers advanced therapeutic options for women facing gynecological cancer. These include single-incision laparoscopic and robotic surgery, targeted therapies based on genomic tumor testing, intraperitoneal chemotherapy and hyperthermic intraperitoneal chemotherapy (HIPEC). HIPEC, in use at Cleveland Clinic's Ob/Gyn & Women's Health Institute since 2011, shows promise for treatment of cancers of the peritoneal cavity arising from gynecologic cancers.

Fairview Family Birth Place: Unique in Northeast Ohio

Cleveland Clinic's Fairview Family Birth Place is a high-touch, low-intervention level I birth center within a level III perinatal center — the only such center in Northeast Ohio and one of only two in Ohio.

Located at Cleveland Clinic Fairview Hospital, the unit is for women seeking a natural childbirth experience, allowing them to remain in the same suite for labor, delivery, recovery and postpartum care. About 24 low-intervention births take place there each month, a number that is growing steadily.

The unit, opened in April 2017, follows new guidance for low-risk pregnancies from the American College of Obstetricians and Gynecologists and endorsed by the American College of Nurse Midwives. The guidelines urge practitioners to consider labor and delivery approaches that use limited medical intervention.

"Patients are admitted to the unit at or beyond 5 cm dilation, and the average length of time from admission

to birth is about five hours," says Sue Hudson, MSN, CNM, Director, Midwifery Services, Cleveland Clinic Western Region. "Women utilize tubs, exercise balls, aromatherapy and continuous support in labor. Midwifery care in collaboration with physicians provides women with the best opportunity to achieve their labor goals. Doulas are welcome if a patient has engaged one." Women have access to nitrous oxide for anxiolysis in active labor.

About 19 percent of patients have been transferred to the labor and delivery unit for augmentation of labor. About 6 percent of these women receive epidurals, Ms. Hudson notes, adding, "Unmedicated birth is very successful, even when patients receive oxytocin. The total cesarean section rate in this very carefully selected, low-risk population is about 2.5 percent. We hope to cut our unscheduled cesarean section rate by half within the next two years.

"We're providing care that reduces risk and cost while increasing satisfaction for patients, families and care-givers," she concludes.

Cardio-Obstetrics Clinic Seeks to Optimize Maternal and Fetal Outcomes

Cardiovascular disease has become the leading cause of maternal mortality in the United States, with approximately 40 percent of maternal deaths attributed to cardiac disease. With decades of medical and surgical advances, an increasing number of women with significant cardiovascular disease are surviving to childbearing age and contemplating pregnancy.

"The significant physiologic stress pregnancy poses for the heart and blood vessels is generally well-tolerated by healthy women," says Jeffrey Chapa, MD, Section Head, Maternal-Fetal Medicine. "However, for women with underlying congenital or acquired heart disease, this added strain can be overwhelming, leading to

significant dysfunction and adverse maternal and fetal outcomes."

The Cardio-Obstetrics Clinic at Cleveland Clinic was developed to improve outcomes through collaborative and coordinated care. Staffed by cardiologists and maternal-fetal medicine specialists, the Cardio-Obstetrics Clinic offers a unique opportunity for





Sue Hudson, MSN, CNM



cardiovascular evaluation related to pregnancy and childbirth. Services offered include preconception consultation and comprehensive pregnancy management, all in the setting of Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute.

The Cardio-Obstetrics Clinic is supported by on-site maternal echocardiography and immediate access to experts in all areas of cardiovascular medicine and surgery. Obstetrical management, including labor and delivery services, occurs in the Special Delivery

Unit, an on-site birthing facility at Cleveland Clinic main campus specifically designed and equipped for maternal critical illness.

Dr. Chapa concludes, "By providing unparalleled resources, convenience and access to subspecialty care, the Cardio-Obstetrics Clinic strives to optimize maternal and fetal outcomes by providing women with cardiac disease an opportunity for education about their underlying condition and informed decision-making regarding their options for childbearing and pregnancy."

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Women's Metabolic Weight Management Program: For Women Struggling to Conceive

The joys and fears of conceiving a baby and anticipating a pregnancy are often magnified for women who struggle with obesity and complications from polycystic ovarian syndrome (PCOS). Chief among the fears are difficulty conceiving, preterm labor, pre-eclampsia, fetal heart defects, gestational diabetes, spontaneous abortion, cesarean-section birth and others.



Karen Cooper, DO

"Weight is such a delicate and sensitive issue," says Karen Cooper, DO, Director, Women's Weight Management Program. "We offer weight management services to assist women who are struggling with PCOS and infertility or other metabolic issues. Achieving a normal body mass index is more challenging for women with PCOS. Having a provider address this is immensely helpful, especially when a woman is trying to conceive.

"Positively changing lifestyle behaviors is about empowering women and helping them break the false idea that their worth is tied to their weight, in addition to helping them achieve long-term health benefits and having a baby," she notes.

Weight loss as fertility treatment

Dr. Cooper first assesses medical needs and determines which "lifestyle path" to recommend. She often recommends a ketogenic diet to promote effective and quick weight loss, in tandem with a fertility specialist's treatment plan.

When pregnancy is achieved, Dr. Cooper recommends continued dietary counseling and guidance from a registered dietitian to help the patient stay within American College of Obstetricians and Gynecologists guidelines for pregnancy weight gain.

Dr. Cooper says the motivation and empowerment her patients gain help them remain compliant. "They are highly motivated and almost always adhere to dietary and exercise regimens," says Dr. Cooper.

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Urogynecology and Pelvic Floor Disorders: Laser Rejuvenation and Natural Orifice Surgery

Pelvic floor or urogynecology surgeons offer a full complement of surgical procedures to correct labial asymmetry, hypertrophy, redundancy and drooping.

“Women who seek vaginal rejuvenation and labiaplasty procedures have symptoms that interfere with quality of life and self-image,” reports Marie Fidela Paraiso, MD, Section Head, Urogynecology and Reconstructive Pelvic Surgery.

Lasers for vaginal atrophy

Increasingly, women with vaginal atrophy are seeking vaginal laser therapy. “When vaginal estrogen is not an option, one or two treatments with a fractional laser (known as the Mona Lisa procedure) can stimulate collagen production in the vaginal epithelium, making sexual intimacy comfortable again,” says Dr. Paraiso.

Natural orifice minimally invasive surgery

Considerable interest in pushing the frontiers of minimally invasive surgery has led to the emergence of a new field in minimally invasive gynecologic surgery. “Natural orifice transluminal endoscopic



surgery, or NOTES, represents one of the most significant innovations in surgery to emerge since the advent of laparoscopy,” reports urogynecology fellow Karl Jallad, MD.

NOTES can be performed via a variety of approaches, including through the stomach, esophagus, bladder and rectum. But the majority of cases are performed transvaginally. Potential advantages of natural orifice surgery in gynecology include the lack of abdominal incisions, less operative pain, shorter hospital stay, improved visibility, and the possibility of circumventing extensive lysis of adhesions to reach the pelvic cavity. NOTES is being performed at Cleveland Clinic in carefully selected cases.

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Chronic Pelvic Pain: Focusing on Research and Patient Experience

Cleveland Clinic’s Ob/Gyn & Women’s Health Institute’s Chronic Pelvic Pain Program, established in 2014, continues to make strides in treating women with chronic pelvic pain, an area that faces a deficit in care nationwide.

“The program has established evidence-based practices to address this broad, complex and often overlapping set of diagnoses,” says Ob/Gyn Mark Dassel, MD, the program’s Surgical Director. “We believe a patient-centered approach, well-defined

research goals and experts from a diverse set of disciplines are needed to address all aspects of chronic pelvic pain.” M. Jean Uy-Kroh, MD, the program’s former Director, now at Cleveland Clinic Abu Dhabi, and Jessica Strasburg, MD, Medical Director, developed the program.

The program’s research database helps guide best practices in chronic pelvic pain management. Three years since the program began caring for patients, several research projects are underway. These include the evaluation of pelvic floor physical therapy outcomes in endometriosis, comparative patient

outcomes at clinics dedicated to chronic pelvic pain treatment and evaluation of optimal intervals for myofascial trigger point injections.

The program operates as a “care home,” meaning patients are not simply moved on to the next specialist but have a consistent team dedicated to reaching patient-identified quality-of-life goals. Centering on the patient experience, the team reviews each patient’s chart prior to arrival so that additional specialists can be consulted, sometimes on the same day. A multidisciplinary team of specialists, including gynecologists, urologists, gastroenterologists, interventional radiologists, anesthesiologists, psychiatrists and pelvic floor physical therapists, meets frequently to discuss disease-specific treatments as well as individual cases.



Mark Dassel, MD

The team plans to develop educational modules for trainees and disease-specific clinical pathways, and to continue advancing evidence-based, multidisciplinary, patient-centered care for women with endometriosis.

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Minimally Invasive Surgery, Education Gain Ground in Benign Gynecology

The Ob/Gyn & Women’s Health Institute has made a concerted effort to increase minimally invasive gynecological surgery (MIGS) training, awareness and adoption both for our own staff and for colleagues around the world.

“We implemented a comprehensive series of hands-on teaching modules in MIGS with simulation for residents,” explains Rosanne M. Kho, MD, Section Head, Benign Gynecology, and Director, Benign Gynecologic Surgery. “In our section, a formalized teaching program schedule provides opportunities for residents and staff members to review the latest evidence and expand their expertise. A master’s course in MIGS (March 2018) will offer hands-on learning in the simulation lab as another effort to increase adoption of minimally invasive surgery (MIS) among Cleveland surgeons.”

For local, national and international colleagues, the institute offered for the first time a CME program titled, “Controversies in Endometriosis, Adenomyosis and Fibroids.” The well-attended conference covered

best practices for managing these complex benign conditions. Cleveland Clinic experts, along with invited international faculty, offered didactic and interactive instructive sessions covering a variety of complex cases.

Clinical pathway developed

“One of our objectives as an institute is to decrease the number of open abdominal hysterectomies,” Dr. Kho comments. To achieve this, the institute developed and implemented a clinical pathway that sets appropriate parameters and provides specific guidelines to help colleagues understand exactly when it is appropriate to refer patients to an MIS surgeon. Imaging protocols for endometriosis and fibroids, developed in close collaboration with radiology colleagues, have also been implemented to improve preoperative diagnosis and the treatment planning process for our patients with these conditions.

“We also work closely with the Endometriosis Center and the Chronic Pelvic Pain Program,” Dr. Kho says. “Together, our areas are dedicated to advancing care for patients with benign gynecological conditions.”

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Rosanne M. Kho, MD

Ob/Gyn residents refine their skills in a dedicated surgical simulation laboratory.



Taking a Leadership Role in Educating Ob/Gyns of the Future

With its four-year residency program and four fellowship tracks, Cleveland Clinic Ob/Gyn & Women's Health Institute plays a leadership role in training future Ob/Gyns. Our trainees go on to become national and international leaders in research and academic medicine as well as successful private practitioners.

For the academic year of July 1, 2016, to June 30, 2017, 23 residents and 14 fellows were enrolled in our advanced training programs.

Residency

Cleveland Clinic's Ob/Gyn residency program, accredited by the Accreditation Council for Graduate Medical Education (ACGME), provides trainees with exceptional educational and clinical experiences, including training with renowned faculty, extensive research projects and exposure to a complex patient population. Physicians receive core training in the fundamentals of obstetrics and gynecology as well as training in gynecologic surgery and women's health issues. With the flexibility of a tailored curriculum, our residents are able to focus early on their subspecialty interests. Residency tracks include female pelvic medicine and reconstructive surgery, specialty Ob/Gyn, global health, gynecologic oncology, maternal-fetal medicine, family planning, and reproductive endocrinology and infertility.

Fellowships

Each Ob/Gyn & Women's Health Institute fellowship is a three-year program.

Gynecologic Oncology This fellowship provides in-depth experience in clinical and investigative work prior to an academic career in gynecologic oncology. It is for trainees who have completed an ACGME-approved residency.



Women's Health This fellowship includes a comprehensive, interdisciplinary curriculum in women's health. The program is administered through the Ob/Gyn & Women's Health Institute and Cleveland Clinic's Medicine Institute, and numerous other departments and institutes participate.

Female Pelvic Medicine and Reconstructive Surgery

Through this fellowship, trainees receive advanced training in the care of patients with female pelvic floor disorders. In-depth experience in clinical and investigative work prepares them for academic careers and leadership roles.

Reproductive Endocrinology and Infertility

Over the course of this fellowship, physicians receive advanced training in the care of patients experiencing all types of fertility issues. Trainees have access to the resources of Cleveland Clinic's In Vitro Fertilization Center and its superb laboratory.

Community Outreach

Cleveland Clinic's Ob/Gyn & Women's Health Institute is committed to community outreach programming for women, including sponsoring two major events and participating in free health fairs, speaking engagements, community education classes, web chats, Facebook Live presentations and women's health clinics.

Celebrate Sisterhood

Energizing and empowering women of color to embrace self-care is the goal of Cleveland Clinic's Celebrate Sisterhood program.

"Celebrate Sisterhood serves both as a catalyst that helps multicultural women self-manage their health and as an advocate for their health transformation," says its Chair and Founder, Linda D. Bradley, MD. Dr. Bradley is Director of the Menstrual Disorders, Fibroids and Hysteroscopic Services Center and Vice Chair of the institute.

The program produces informative seminars and an annual summit that attract women from across Northeast Ohio. Celebrate Sisterhood's website (clevelandclinic.org/celebratesisterhood) offers treatment guides and multicultural women's health information.

In 2017, Celebrate Sisterhood's annual women's health and wellness summit drew nearly 800 attendees. Speakers from Cleveland Clinic presented a multitude of topics: understanding new guidelines for breast screening and mammography, how to maintain healthy skin and hair, resilience training, stress management, and bouncing back from adversity. Participants in record numbers took advantage of health screenings.

"Throughout the day, attendees learned the importance of culinary and nutritional literacy and the importance of adherence to immunization schedules, routine screenings, and the need to have a primary care physician," Dr. Bradley says. "They learned that countless medical conditions are preventable and reversible through diet and exercise. Celebrate Sisterhood prepares women to be beacons of change in our communities."

As in previous years, the Celebrate Sisterhood Summit was streamed live to the Ohio Reformatory for Women, one of the nation's largest prisons for women.

Speaking of Women's Health

Speaking of Women's Health (SWH), a women's health digital platform and national nonprofit organization, educates women and empowers them to make informed decisions about health, well-being and personal safety. Holly L. Thacker, MD, is Director and Professor, Center for Specialized Women's Health, and SWH's Executive Director.


With more than 40,000 members and several partners, SWH features an award-winning website (speakingofwomenshealth.com) where online visitors can find a health library, breaking health news, treatment guides, an "Ask The Nurse" question-and-answer column, recipes, e-newsletters (reaching more than 40,000 women nationwide), webchats and Facebook Live events — all at no charge.

SWH events in communities across the country have offered expert speakers, health screenings, nutritional advice and informational sessions to women, healthcare systems and employers. Many event offerings are now extended digitally via the organization's website.

"SWH gives women access to a broad range of health services available through Cleveland Clinic's Center for Specialized Women's Health," Dr. Thacker notes. The center offers highly individualized CustomFit Physicals for Women that combine convenience with comprehensiveness, and also provides an innovative pelvic floor stimulation program.

"Women are at the center of health in their families and communities," she continues. "They make 80 percent of healthcare decisions. The Speaking of Women's Health platform provides information from credible experts in a fun and entertaining way, helping women take better care of themselves and their families. Our motto is 'Be Strong. Be Healthy. Be in Charge!'"





Continuing Medical Education

The Ob/Gyn & Women's Health Institute presented the continuing medical education (CME) program, "Controversies in Endometriosis, Adenomyosis and Fibroids" in August. The two-day comprehensive course featured institute experts and speakers from around the world and attracted a national and international audience. Institute physicians also presented at the September CME "Genetics & Genomics: A Focus on Women's Health," co-sponsored by Cleveland Clinic's Genomic Medicine Institute and Center for Personalized Genetic Healthcare.

Marjan Attaran, MD, Section Head, Pediatric and Adolescent Gynecology, speaking at a 2017 CME program.

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Ob/Gyn & Women’s Health Institute

At a Glance

**12 centers and programs at 36 locations
across the region and in Florida**

Chronic Pelvic Pain

Endometriosis

Fertility

General Gynecology

Gynecologic Infectious Diseases

Gynecologic Oncology

Maternal-Fetal Medicine

**Menstrual Disorders, Fibroids and
Hysteroscopic Services**

Obstetrics and Family Maternity

Specialized Women's Health

Urogynecology and Pelvic Floor Disorders

Women’s Weight Management

\$1.9 million in new research funding

The Ob/Gyn & Women’s Health Institute provides a robust infrastructure for the conduct of high-impact studies through research support and career development of physician-researchers. With \$1.9 million in new research funding and a steadily growing number of publications and new studies, 2017 was a very successful and productive year. Research collaborations are expected to expand and strengthen in coming years. Ruth Farrell, MD, serves as Vice Chair of Clinical Research for the institute.

Statistics reported are from July 1, 2016, to June 30, 2017.

Caregivers

Ob/Gyns	155
Certified nurse midwives	20
Advanced practice nurses	37
Residents	23
Fellows	14

120 Publications

Books:

Clinical Reproductive Medicine and Surgery: A Practical Guide, Third Edition

Editors, Tommaso Falcone, MD,
and William Hurd, MD. (Springer)

Operative Techniques in Gynecologic Surgery: Gynecology

Editor, Tommaso Falcone, MD;
Associate Editors, M. Jean Uy-Kroh,
MD, and Linda D. Bradley, MD.
(Wolters Kluwer)



Patient activity

Hospital admissions	10,128
Surgical procedures performed*	9,031
Deliveries	9,499
Outpatient visits	425,864
Shared medical appointments	799
Virtual visits	109

*excludes c-sections

Shared medical appointments

Cleveland Clinic's Ob/Gyn & Women's Health Institute offers shared medical appointments in these centers:

Fertility | General Gynecology | General Obstetrics and Family Maternity | General Obstetrics and Gynecology, Florida | Menstrual Disorders, Fibroids and Hysteroscopic Services | Specialized Women's Health | Urogynecology and Pelvic Floor Disorders | Women's Weight Management

Virtual visits

Virtual visits allow patients to communicate in real time (audio and video) with their providers from their home, office or elsewhere via a computer or smartphone. The Ob/Gyn & Women's Health Institute offers virtual visits for its Metabolic Weight Management Program and for new, follow-up and postoperative visits in a variety of services.

In 2017, we piloted a program that combined virtual visits and shared medical appointments in a program for medical weight management. Our first cohort of seven patients achieved a combined weight loss of approximately 145 pounds over six weeks. The program will be offered again in 2018

Mariam AlHilli, MD

Resources for Physicians

Consult QD — Ob/Gyn & Women’s Health

News, research and perspectives from Cleveland Clinic experts:
consultqd.clevelandclinic.org/obgyn

Ob/Gyn ePerspectives

To subscribe, visit:
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Outcomes Data

clevelandclinic.org/outcomes

CME Opportunities

Visit ccfcme.org for offerings from Cleveland Clinic’s Center for Continuing Education.

Ob/Gyn & Women's Health Institute

2017 Year in Review

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Ob/Gyn & Women's Health Institute's *2017 Year in Review* is written for physicians and should be relied on for medical education purposes only. It does not provide a complete overview of the topics covered and should not replace the independent judgment of a physician about the appropriateness or risks of a procedure for a given patient.



Every life deserves world class care.

9500 Euclid Ave., Cleveland, OH 44195

The Ob/Gyn & Women's Health Institute provides a full spectrum of care for women from adolescence through mature adulthood. Institute members provide collaborative care for gynecological cancers, infertility, incontinence, pelvic floor disorders and other women's health issues in a supportive environment enhanced by innovative research. The Ob/Gyn & Women's Health Institute is one of 27 clinical and special expertise institutes at Cleveland Clinic, a nonprofit academic medical center ranked as the No. 2 hospital in the country by *U.S. News & World Report*. More than 3,500 staff physicians and researchers in 140 specialties at Cleveland Clinic collaborate to give every patient the best outcome and experience. clevelandclinic.org

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